DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

March 17, 1999

Ref: 99-DAL-WL-12

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Arrie Kegler
Founder and CEO
Kegler's Vending Service
300 East Ledbetter D-8
Dallas, Texas 75216

Ref: Keg's Arthritis Relief Formula
Keg's Breath EEE ZZZ

Dear Mr. Kegler:

This is in reference to the above listed products which are manufactured and distributed by your firm. The labeling for **KEG'S ARTHRITIS RELIEF FORMULA** makes the following claims.... "will stop any pain in less than 3 minutes and without any side effects...will reduce the swelling in an hour or less...will stop cancer pain without side effects... effectively relieves pain for many types of arthritis, the gout, bursitis, and tendonitis." The labeling for **Keg's Breath EEE ZZZZ** makes the following claim: "Formula For Asthma." The labels for both state "Contents: A Unique Blend of Herbs and Vitamin C...Sodium 310mg...Potassium 50mg...Acetic Acidity 3.0...238 Scoville Units."

Based on their intended uses, these products are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. We do not have any information which shows that your products, or similarly labeled and formulated over-the-counter (OTC) drugs, were marketed in the United States prior to December, 1975. We do not know of any substantial scientific evidence which demonstrates that your products are generally recognized as safe and effective for their intended uses.

Based on the information cited above, we consider these products to be "new drugs" (Section 201(p) of the Act) that may not be legally marketed in this country unless they have approved new drug applications (Section 505 of the Act). These products are misbranded (Section 502(f)(1) of the Act) because their labeling fails to bear adequate directions for use.

The above list of violations is not intended to be an all inclusive list of deficiencies for products marketed by your firm. It is your responsibility to ensure that the drug products you manufacture and distribute are in compliance with federal law and regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices, so they might take this information into account when considering the award of contracts.

Failure to promptly correct these violations and prevent future violations may result in regulatory action without further notice such as seizure and/or injunction. Within fifteen (15) days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of the violation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Dallas District Office, at the above letterhead address, Attention: Reynaldo R. Rodriguez, Jr., Compliance Officer.

Sincerely,

Sylvia G. Yett

for Joseph R. Baca
Dallas District Director

JRB:RRR:jab